REMARKS/ARGUMENTS

Claims 1-10 and 24 are currently pending. Claims 1-10 and 24 stand rejected. Claims 1, 7, and 24 have been amended to further clarify the present invention and is supported in the specifciation and drawings. No new matter has been added.

RESPONSE

The 35 U.S.C. § 102 Rejection

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Burney et al[1]. This rejection is respectfully traversed.

According to the M.P.E.P., a claim is anticipated under 35 U.S.C. § 102(a), (b) and (e) only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.[2]

The Office Action specifically states:

> "Burney discloses a system comprising a catheter with a closed distal end (tip 30) and a side port (lateral opening 24) adjacent the distal end and an adaptor (needle hub 17) connected to the catheter having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter, and wherein the adaptor is removable from the catheter (page 16, lines 20-25)."[3]

The Examiner equates the adaptor to the needle hub (17) of Burney. Applicant respect disagrees.

Amended Claim 1 provides for the following limitations:

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[1] WO 97/28746
[2] Manual of Patent Examining Procedure (MPEP) § 2131. See also *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).
[3] Office Action ¶ 2.

> "an adaptor connected to the catheter designed to hydrate and deliver the pledget to the catheter, the adaptor having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter, and wherein the adaptor is removable from the catheter."

As stated in the Specification and as claimed in claim 1, the catheter is "for delivering a pledget of sponge material in a hydrated state to the tissue". (See, Specification, page 16, paragraph 63). Moreover, as stated in the Specification and as claimed in claim 1, the **adaptor** is "connected to the catheter for hydrating and delivering the pledget to the catheter." (See Specification page 7, paragraph 40; page 8, paragraph 41).

Burney merely teaches a biopsy guide "which provide safe and efficient coaxial, cofocal and eccentric sampling or delivery with only a single guide device placement." (Page 1, lines 5-7). Burney teaches that the use of a "handle 71 may include a locking hub 72 which mates with a notch (not shown) on the biopsy needle hub 17 for locking the biopsy stylet into place." (Page 19, lines 24-26). Upon a closer reading of Burney and review of the figures, the biopsy needle hub 17 is merely used to lock the biopsy stylet into place on the handle. The biopsy needle hub is not used to hydrate or deliver a pledget to a catheter as claimed in claim 1. In fact, the biopsy needle hub would not be able to perform the function of the adaptor of the present invention since the biopsy needle hub and the adaptor are two completely different structures. (Compare Fig. 2 of the present invention versus Fig. 7 of Burney).

Thus, it can not be said that the present invention is anticipated by Burney. Applicant respectfully requests that this rejection be withdrawn.

The 35 U.S.C. § 103 Rejection

Claims 7-10 and 24 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Burney in view of Nabai et al.[4] This rejection is respectfully traversed.

According to M.P.E.P. §2143,

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in the applicant's disclosure.

Amended Claim 7 provides for the following:

> A system for injecting a sponge into tissue, the system comprising:
>
> a catheter having a closed distal end and a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue;
>
> an adaptor connected to the catheter designed to hydrate and deliver the pledget to the catheter, the adaptor having a tapered lumen with a large diameter proximal end and a small diameter distal end, wherein the small diameter distal end is connected to the catheter; and
>
> a pledget of sponge material preloaded in the adaptor.

Amended Claim 24 provides for a similar limitation.

The Office Action states:

> "Burney discloses the claimed invention except for the pledget of absorbable sponge material loaded in the adaptor."

Applicant respectfully disagrees that Burney discloses the claimed invention. The Examiner equates the adaptor of the present invention to the needle hub (17) of Burney. As discussed in detail above, Burney does not disclose the claimed invention since the needle hub can not be equated to the adaptor.

The Office Action further states:

> "Nabai teaches that a sponge is delivered in order to promote healing without the necessity of suturing (Column 3 lines 11-18). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Burney with a sponge in order to promote healing in the biopsy location without the need for sutures."

Applicant respectfully disagrees.

i. There is No Suggestion or Motivation to Combine the Prior Art References

There is no suggestion or motivation to combine Burney with Nabai. Burney teaches a "guide . . . for biopsy and microtherapy which includes an introducer cannula defining a lumen sized to receive a diagnostic or therapeutic item . . . and a lateral opening in communication with the lumen adjacent the first end of the cannula. The invention also has a solid tip." (Abstract).

Nabai teaches the use "of a syringe, a detachable needle mounted on one end portion of the syringe, a biopsy punch attached to the same end portion which is accessible only when the needle is removed from the syringe, and a small pad of an absorbable sponge. The needle is removed from the syringe after a patient has been anesthetized with the syringe to expose the biopsy punch. A biopsy specimen is excised with the punch. Thereafter, a cylindrical plug is cut from the pad of absorbable sponge with the biopsy punch and implanted into the biopsy site."

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[4] U.S. Patent 5,325,857.

(Abstract). "The punch 22 is a thin cylindrical blade with a sharp end portion 27." (Col. 2, lines 55-16). Thus, the syringe in Nabai is used to merely draw-up and inject anesthesia and not to hydrate and inject a sponge through. Rather, the needle is removed from the patient, the biopsy specimen is taken, and then the pledget is expelled mechanically.

Burney merely teaches a guide for a biopsy device whereas Nabai discloses a biopsy device itself. There is no suggestion or motivation to combine the two prior art references since the syringe of Nabai could not and would not fit into the guide device of Burney. Moreover, the combination of Burney and Nabai would not result in a working device since Burney teaches a guide having a solid tip whereas Nabai teaches a punch having a thin cylindrical blade to excise the biopsy specimen.

Thus, there is no motivation or suggestion to combine the references.

ii. There is No Reasonable Expectation of Success.

The present invention, as claimed in amended Claim 7, provides for:

"a catheter having a closed distal end and a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue; and

an adaptor connected to the catheter designed to hydrate and deliver the pledget to the catheter . . . ; and

a pledget of sponge material preloaded in the adaptor."

The present invention utilizes an adaptor connected to the catheter to hydrate and deliver the pledget to the catheter. Neither Burney nor Nabai teach the use of an **adaptor** nor do they teach or suggest the delivery of a **hydrated** pledget to a catheter for delivery of the pledget in a

hydrate state to the tissue. Furthermore, the devices of Burney and Nabai could not hydrate and inject a pledget.

Thus, the alleged combination of the prior art references would not result in the claimed invention. In fact, the alleged combination would not even result in a viable, working biopsy device. Therefore, since the alleged combination of the prior art references would not result in the claimed invention, they can not be said to render the claimed invention obvious.

iii. The prior art references, when combined, do not teach or suggest all the claim limitations

As described above, independent amended Claim 7 provides for:

"a catheter having a closed distal end and a side port adjacent the distal end for delivering a pledget of sponge material in a hydrated state to the tissue; and

an adaptor connected to the catheter designed to hydrate and deliver the pledget to the catheter . . . ; and

a pledget of sponge material preloaded in the adaptor."

As discussed above, the present invention utilizes an adaptor to hydrate and deliver the pledget to the catheter for delivery of the pledget, in a hydrated state, to the tissue. As provided for in Claim 7, the pledget is preloaded in the adaptor.

Additionally, as discussed above, neither Burney nor Nabai teach or suggest the use of an adaptor or the delivery of a hydrated pledget to the tissue. Nor is the "adaptor" of Burney capable of having a sponge preloaded in it.

Thus, since the prior art references, when combined, does not teach or suggest all the claim limitations, they can not be said to render the claimed invention obvious.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance. It is respectfully requested that this rejection be withdrawn.

Remaining Independent and Dependent Claims

All dependent claims depend from independent claims 1, 7, and 24 and thus include the limitations of their respective corresponding base claim. The base claims being allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

It is believed that this Amendment places the above-identified patent application into condition for allowance. Early favorable consideration of this Amendment is earnestly solicited.

Several attempts to contact the Examiner have been unsuccessful. Thus, if a notice of allowance will not be issued, to expedite the prosecution of this application, it is respectfully requested that the Examiner call the undersigned attorney at the number indicated below.

The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 50-1698.

Respectfully submitted,
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